525 Rec'd PCT/PTO FORM PTV-1390 (Modified) (REV 11-98) U.S. DEPARTME F COMMERCE PATENT AND TRADEMARK OFFICE 2.72.7-TRANSMITTAL LETTE O THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.5 CONCERNING A FILING UNDER 35 U.S.C. 371 INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED PCT/EP99/03554 25 May 1999 (25.04.99) 22 May 1998 (22.05.98) TITLE OF INVENTION TIME-CONTROLLED-RELEASE ACTIVE-INGREDIENT-CONTAINING TRANSDERMAL SYSTEMS APPLICANT(S) FOR DO/EO/US Wilfried Fischer Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: 1. X This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371. 2. This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371. 3. This is an express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1). A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date. 4. \mathbf{X} 5. A copy of the International Application as filed (35 U.S.C. 371 (c) (2)) a. 🔀 is transmitted herewith (required only if not transmitted by the International Bureau). b. □ has been transmitted by the International Bureau. c. 🗆 is not required, as the application was filed in the United States Receiving Office (RO/US). A translation of the International Application into English (35 U.S.C. 371(c)(2)). X A copy of the International Search Report (PCT/ISA/210). -8 Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3)) are transmitted herewith (required only if not transmitted by the International Bureau). b. 🗆 have been transmitted by the International Bureau. c. 🗆 have not been made; however, the time limit for making such amendments has NOT expired. 2 d. 🔀 have not been made and will not be made. A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 10. An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)). ĹĪ A copy of the International Preliminary Examination Report (PCT/IPEA/409). 12. A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)). Items 13 to 20 below concern document(s) or information included: 13. An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 14. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 15. \mathbf{X} A FIRST preliminary amendment. 16. A SECOND or SUBSEQUENT preliminary amendment. 17. A substitute specification. 18. A change of power of attorney and/or address letter. 19. Certificate of Mailing by Express Mail 20. X Other items or information:

Page 1 of 2

WIPO publication cover page

Declaration (unsigned)

PCTUS1/REV03

532 Rec'd PCT/PTO U.S. APPLICATION INTERNATIONAL APPLICATION NO. PCT/EP99/03554 2727-130 21. The following fees are submitted:. CALCULATIONS PTO USE ONLY BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) : Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2) paid to USPTO and International Search Report not prepared by the EPO or JPO \$970.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but Internation Search Report prepared by the EPO or JPO ... \$840.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$690.00 International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4)..... \$670.00 International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4)...... \$96.00 ENTER APPROPRIATE BASIC FEE AMOUNT = \$860.00 Surcharge of \$130.00 for furnishing the oath or declaration later than \$0.00 **CLAIMS** NUMBER FILED NUMBER EXTRA RATE \$18.00 Total claims \$0.00 16 -20 =x 3 = 0 x \$78.00 \$0.00 Independent claims Multiple Dependent Claims (check if applicable). \$0.00 \Box TOTAL OF ABOVE CALCULATIONS \$860.00 Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement dust also be filed (Note 37 CFR 1.9, 1.27, 1.28) (check if applicable). \$430.00 SUBTOTAL \$430.00 Processing fee of \$130.00 for furnishing the English translation later than □ 20 □ 30 \$0.00 TOTAL NATIONAL FEE \$430.00 Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable). \$0.00 TOTAL FEES ENCLOSED \$430.00 Amount to be: refunded ľU Ö \$ charged A check in the amount of to cover the above fees is enclosed. X Please charge my Deposit Account 501145 in the amount of \$430.00 to cover the above fees. A duplicate copy of this sheet is enclosed. X The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. A duplicate copy of this sheet is enclosed. 501145 NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met 1.137(a) or (b)) must be filed and granted to restore the application to pending status. SEND ALL CORRESPONDENCE TO: Ronald R. Santucci SIGNATURE Pitney, Hardin, Kipp & Szuch, LLP 711 Third Avenue, 20th Floor Ronald R. Santucci New York, New York 10017 NAME REGISTRATION NUMBER (212)687-6000 November 15, 2000 DATE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

I, MOIRA ANN DLUGOSZ, B.A., declare

- That I am a citizen of the United Kingdom of Great Britain and Northern Ireland, residing at Warham Lodge, Ford Road, Dinton, Aylesbury, Buckinghamshire, HP17 8UG.
- 2. That I am well acquainted with the German and English languages.
- 3. That the attached is a true translation into the English language of the claims of International Patent Application No. PCT/EP 99/03 554 as amended in the international phase.
- 4. That all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such wilful false statements may jeopardise the validity of the patent application in the United States of America or any patent issuing thereon.

DECLARED THIS 264L DAY OF Och ber

2000

M. A. DLUGOSZ